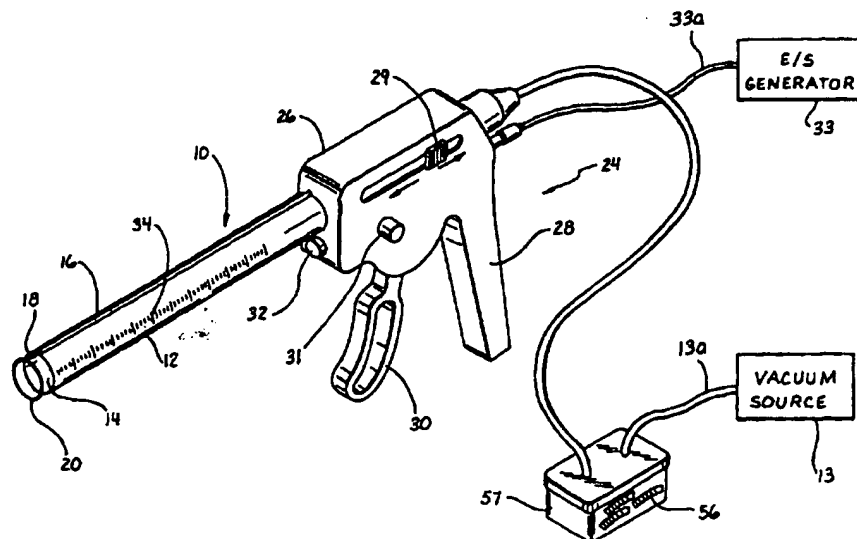




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(54) Title: METHODS AND DEVICES FOR COLLECTION OF SOFT TISSUE



(57) Abstract

This invention provides an inventive tissue sampling probe which offers many advantages over probes available in the prior art. Unexpectedly superior results are obtained in connection with the retrieval of intact tissue specimens, because of a unique combination of cutting features, including, for example, the employment of an electrosurgical cutting element and a vacuum assist in one preferred embodiment. A particularly important feature of the invention is the ability to manipulate the electrosurgical cutting element to cleanly sever the distal end of the tissue specimen. In certain embodiments, this is accomplished without any cutting impact on surrounding tissue. The versatility of the invention permits its use in many applications, including, for example, breast biopsies, laparoscopic surgery, and lymphadenectomy procedures.

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METHODS AND DEVICES FOR COLLECTION OF SOFT TISSUE

Field of the Invention

The present invention relates to methods and devices for tissue sampling, and more specifically to improved instruments and methods for acquiring soft body tissue.

Background of the Invention

It is often desirable and frequently necessary to sample or test a portion of tissue from humans and other animals, particularly in the diagnosis and treatment of patients with cancerous tumors, pre-malignant conditions, and other diseases or disorders.

Typically, in the case of breast cancer, there is a great emphasis on early detection and diagnosis through the use of screening modalities, such as physical examination, and particularly mammography, which is capable of detecting very small abnormalities, often nonpalpable. When the physician establishes by means of a mammogram or other screening modality that suspicious circumstances exist, a biopsy must be performed to capture tissue for a definitive diagnosis as to whether the suspicious lesion is cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy, which is an invasive surgical procedure using a scalpel and involving direct vision of the target area, removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy, on the other hand, is usually done with a needle-like instrument through a relatively small incision, blindly or with the aid of an artificial imaging device, and may be either a fine needle aspiration (FNA) or a core biopsy. In FNA biopsy, individual cells or clusters of cells are obtained for cytologic examination and may be prepared such as in a Papanicolaou smear. In core biopsy, as the term suggests, a core or fragment of tissue is obtained for histologic examination which may be done via a frozen section or paraffin section.

The type of biopsy utilized depends in large part on circumstances present with respect to the patient, including the location of the lesion(s) within the body, and no single procedure is ideal for all cases. However, core biopsy is extremely useful in a number of conditions and is being used more frequently by the medical profession.

A very successful type of image guided percutaneous core breast biopsy instrument currently available is a vacuum-assisted automatic core biopsy device. One such successful biopsy device is shown and disclosed in U.S. Patent No. 5,526,822, U.S. Patent Application Serial Number 08/386,941, filed on February 10, 1995, and U.S. Patent Application Serial Number 08/568,143, filed on December 6, 1995, all of which are commonly owned by the assignee of the present application and are herein incorporated by reference. This device, known commercially as the MAMMOTOME® Biopsy System, has the capability to active capture tissue prior to cutting the tissue. Active capture allows for sampling through non-homogeneous tissues, meaning that the device is equally capable of cutting through hard and soft tissue. The device is comprised of a disposable probe, a motorized drive unit, and an integrated vacuum source. The probe is made of stainless steel and molded plastic and is designed for collection of multiple tissue samples with a single insertion of the probe into the breast. The tip of the probe is configured with a laterally disposed sampling notch for capturing tissue samples. Orientation of the sample notch is directed by the physician, who uses a thumbwheel to direct tissue sampling in any direction about the circumference of the probe. A hollow cylindrical cutter severs and transports tissue samples to a tissue collection chamber for later testing.

While the MAMMOTOME Biopsy System functions very well as a core biopsy device, there are occasions when, because of the size of a lesion, or its location, it may be advantageous to use a core biopsy device of a type disclosed in U.S. Patent No. 5,111,828, to Kornberg et al., also expressly incorporated by reference herein, wherein the tissue receiving port is disposed at the distal end of the device and is oriented axially rather than laterally. A disadvantage of this type of device, however, is the lack of ability to effectively and efficiently draw tissue into the receiving chamber prior to and during the tissue cutting process. A second disadvantage is the requirement to withdraw the device from parent tissue and

remove the first specimen, reassemble the device, then reintroduce the device for each desired specimen. A third disadvantage is the necessity of manually handling each specimen obtained.

5 On other occasions, the ability to sample any selected area of a cavity wall from within the cavity may be important, which ability requires the use of a flexible probe.

Furthermore, it is desirable during the biopsy process to "stage" the spread of a cancer. For example, breast cancer starts in the milk ducts, the mammary glands. The initial change towards breast cancer is now thought to be the
10 development of atypical ductal hyperplasia. The next step is thought to be represented by ductal carcinoma in situ. Finally, the last step in the development of breast cancer is infiltrating ductal carcinoma. By the time the breast cancer has reached the stage of infiltrative ductal carcinoma, breast cancer cells have developed the ability to migrate from the duct of origin, disassociate themselves
15 from one another, and enter vascular structures, such as the lymphatic channels. When these malignant infiltrative ductal carcinoma cells enter the vascular system, they can spread or metastasize to other parts of the body. It is this metastatic process that ultimately leads to death from breast cancer.

When breast cancer cells enter the lymphatic system, they metastasize in an
20 orderly fashion to regional lymph nodes. Drainage can occur to the axillary lymph nodes, the supraclavicular lymph nodes, the lateral thoracic lymph nodes, and to the internal mammary lymph nodes.

It is the current standard of practice to determine if breast cancer cells have extended to regional lymph nodes by surgically performing an axillary lymph node
25 dissection known as lymphadenectomy. In this open surgical procedure, a relatively large incision (5-10 cm), is made at the axilla (the armpit). Through this incision, a relatively large volume (15 to 30 grams) of fatty tissue and lymph node tissue are removed.

During this process, anywhere from 10 to 30 lymph nodes can be recovered
30 and submitted to pathology, where each of these lymph nodes is examined for the presence or absence of metastatic breast cancer. Based on positive lymph node findings, systemic therapy will be given to the patient with breast cancer, including

chemotherapy. If, on the other hand, the lymph nodes of the axilla are free of metastatic disease, then the use of systemic therapies is limited.

5 Surgical lymphadenectomy carries a low mortality, but high morbidity. The most common morbidity is the development of lymph edema in the arm, which is ipsilateral to the axilla dissected. The development of lymph edema in the ipsilateral arm is, at times, a debilitating complication.

10 It has been shown in the examination of lymphatic drainage of melanoma, and now shown in the lymphatic drainage of breast cancers, that lymphatic drainage patterns can be defined by the injection of a radioisotope (or other traceable marker such as blue dye) into the bed of the tumor. The isotope (or dye) is then followed, either visually, with a gamma camera imaging system, or with a Geiger counter-type of counting system.

15 The spread of cancer cells is orderly, the first lymph node reached by the drainage channels from the infected breast containing the most cancer cells. Consequently, the first lymph node in the draining system is referred to as the "sentinel" lymph node.

20 It has been further shown, if one simply removes the sentinel lymph node, the determination of whether or not breast cancer has metastasized to the regional lymph nodes of the axilla can be established without excision of the remaining lymph nodes in the axilla. The surgical removal of only one lymph node greatly reduces the complications of lymph node surgery including the morbidity of lymph edema.

25 It would be desirable to further reduce the morbidity of the axillary sentinel lymph node biopsy if instrumentation were available to allow the sentinel lymph node to be identified and removed percutaneously with as little effect as possible to the surrounding tissue structure. The apparatus described in this patent can be introduced percutaneously through a small skin opening and directed to the sentinel lymph node thus eliminating open surgical exploration. Consequently, sentinel lymph node biopsy could be accomplished as an office procedure, eliminating hospitalization and minimizing the recovery period.

30 The elements of a percutaneous sentinel lymph node biopsy are as follows: The tumor site in the breast is injected with a radioisotope (such as technicium 99m labeled sulfur colloid) which travels via the lymphatic channels to the sentinel

lymph node. The sentinel lymph node then becomes radioactively visible, or "hot." The apparatus hereafter described is able to identify or locate the radioactive lymph node through auditory and other signals, indicating when the apparatus is adjacent to the sentinel lymph node. The apparatus is further able to then characterize or
5 "visualize" the surrounding tissue with the associated ultrasound portion of the apparatus. It is important to identify the associated structures adjacent to the lymph node, because relatively large blood vessels (arteries, veins,) and nerves traverse the axilla. With the combination of percutaneous Geiger counter identification and percutaneous ultrasound identification, the sentinel lymph node can be identified
10 and biopsied without entering a major blood vessel or severing a major nerve.

With a small entry site, no suturing would be required (the procedure would be percutaneous), and the patient could be sent home with a simple band-aid over the axillary entry site. The following day, the patient would receive the results of the percutaneous sentinel lymph node biopsy determining whether or not metastatic
15 disease is present or absent in the sentinel lymph node draining the affected breast.

Instruments are known in the prior art which could be adapted to perform some of the procedures outlined above. For example, U.S. Patent No. 5,111,828 to Kornberg et al. discloses a percutaneous excisional breast biopsy device having a cannula, open distal and proximal ends, and a sharp cutting surface on the distal
20 end. A stylet extends through the cannula and includes a distal puncturing end. A localization guide wire is used to direct the instrument to a biopsy site. The cannula is moved distally to cut a desired tissue specimen, after which a descending element is pushed to the distal end of the tissue specimen, then pulled proximally to sever the specimen completely from surrounding tissue.

A significant disadvantage of the Kornberg approach is that only one tissue sample may be obtained for each insertion of the instrument into the patient's body to the biopsy site. Once the descending element has been pulled to sever the tissue sample, there is no opportunity to repeat the procedure while the instrument remains in place. Also, no means is provided to ensure that tissue to be sampled is
25 drawn toward the distal end of the cannula 2 (or "actively captured"), thereby
30 reducing tissue sampling efficiency.

The present invention lacks the disadvantages and shortcomings of the prior art and provides an improved method and device for percutaneous excisional tissue

biopsy. The present invention may be used for purposes others than percutaneous biopsy. For example, the device may be used for general organ and tissue removal through a trocar to perform various laparoscopic procedures including splenectomy, nephrectomy, appendectomy and liver removal. The device may also be used
5 laparoscopically through a trocar to remove abnormal growths such as polyps.

Summary of the Invention

This invention provides an inventive tissue sampling probe which offers
10 many advantages over probes available in the prior art. Unexpectedly superior results are obtained in connection with the retrieval of intact tissue specimens, because of a unique combination of cutting features, including, for example, the employment of an electrosurgical cutting element and a vacuum assist in one preferred embodiment. A particularly important feature of the invention is the
15 ability to manipulate the electrosurgical cutting element to cleanly sever the distal end of the tissue specimen. In certain embodiments, this is accomplished without any cutting impact on surrounding tissue. The versatility of the invention permits its use in many applications, including, for example, breast biopsies, intraoperative staging, laparoscopic surgery, and lymphadenectomy procedures.

20 More particularly, the invention provides a tissue sampling apparatus which comprises a tubular body having a primary lumen for receiving a tissue sample. The tubular body includes a distal end and a proximal end. An electrosurgical cutting element is provided, which is non-rotating during the cutting procedure in order to preserve the integrity of the tissue samples, though it may be rotatably
25 pivoted across the tubular cross-section at the conclusion of the cutting process in order to sever the distal end of the tissue sample. In certain preferred embodiments, the electrosurgical cutting element comprises a wire disposed distally of the distal end of the tubular body. A means for drawing tissue to be sampled into the primary lumen is also provided, whereby the electrosurgical cutting element
30 cuts the tissue to capture an intact tissue sample core within the primary lumen.

In a preferred embodiment, the means for drawing tissue into the lumen comprises a source of vacuum pressure for drawing a vacuum through the primary lumen, the vacuum pressure in the primary lumen drawing tissue to be sampled into

the primary lumen and the electrosurgical cutting element cutting the tissue to capture an intact tissue sample within the primary lumen. The vacuum pressure then acts to transport the specimen proximally through the primary lumen to a tissue receptacle.

5 In one particular aspect of the invention, the tubular body is relatively flexible, rather than relatively rigid, so that the tubular body is steerable to obtain tissue samples from any desired location on the wall of a tissue cavity. In such an embodiment, the apparatus is deliverable to the tissue cavity, which is typically a void formed by the removal of tissue during a biopsy procedure, using a
10 percutaneous access device.

 In another particular aspect of the invention, a method of capturing a body tissue sample using a tissue sampling apparatus is provided, wherein the tissue sampling apparatus comprises a tubular body having a lumen extending
15 therethrough, a distal end, an electrosurgical cutting element disposed distally of the distal end of the tubular body, an actuator for moving the cutting element, and an electrocautery generator. The method comprises the steps of activating the electrocautery generator to energize the electrosurgical cutting element, advancing the tubular body through a tissue portion a desired distance so that the energized electrosurgical cutting element cuts a tissue sample core as the tissue sample enters
20 the lumen, and actuating the electrically energized cutting element so that it moves across at least a portion of the cross-sectional area of the tissue sample core at its distal end. This movement of the cutting element functions to sever the distal end of the tissue sample to thereby capture the tissue sample core in a substantially intact condition within the tubular body lumen.

25 The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawing.

Brief Description of the Drawing

30

 Fig. 1 is a perspective view of a first preferred embodiment of the inventive tissue sampling instrument;

Fig. 2 is a perspective view illustrating the distal end of the inventive instrument shown in Fig. 1;

5 Fig. 3 is a perspective view similar to that of Fig. 2, illustrating the conductive cutting hoop of the Fig. 1 embodiment displaced in a first direction;

Fig. 3a is an end elevation view illustrating the conductive cutting hoop displaced in the first cutting direction;

10 Fig. 4 is a perspective view similar to Figs. 2 and 3, illustrating the conductive cutting hoop in the process of being displaced from the first cutting direction to a second cutting direction opposite to the first cutting direction shown in Figs. 3 and 3a;

15 Fig. 4a is an end elevation view similar to that of Fig. 3a, illustrating the conductive cutting hoop displaced in the second cutting direction;

20 Fig. 5 is a perspective view of a modified embodiment of the distal end of the inventive instrument, illustrating the conductive cutting hoop in a retracted position;

Fig. 6 is a perspective view of the modified embodiment of Fig. 5, illustrating the conductive cutting hoop in an axially extended position;

25 Fig. 7 is a perspective view of a second modified embodiment of the distal end of the inventive instrument, wherein the support stem for the conductive cutting hoop, shown in its retracted position, is preformed to a predetermined non-linear shape;

30 Fig. 8 is a perspective view of the second modified embodiment, similar to Fig. 7, showing the conductive cutting hoop in an extended non-linear position;

Fig. 9 is a perspective view of a second preferred embodiment of the inventive tissue sampling instrument, illustrating a flexible probe which is adapted for percutaneous deployment into a body cavity through an established working port;

5

Figs. 10 and 10a are perspective views illustrating the distal end of the embodiment shown in Fig. 9;

Fig. 11 is an enlarged elevational schematic view of the distal portion of the flexible probe illustrated in Fig. 9;

10

Fig. 12 is an elevational view similar to that of Fig. 11, illustrating the receipt of a tissue specimen within the distal end of the flexible probe;

15

Fig. 13 is a perspective view of the embodiment of Fig. 1, illustrating an optional inventive feature for accommodating a plurality of tissue samples;

Fig. 14 is a schematic cross-sectional view illustrating the interior of a tubular portion of the tissue sampling device shown in Fig. 13, illustrating the use of a movable stop plunger to permit the receipt of multiple tissue specimens and to prevent the specimens from being suctioned proximally to a source of vacuum utilized to draw tissue samples into the inventive device;

20

Fig. 15 is a perspective view similar to that of Fig. 1, illustrating a third preferred embodiment of the inventive tissue sampling device;

25

Fig. 16 is a perspective view of the distal or business end portion of the Fig. 15 embodiment;

30

Fig. 17 is a perspective view similar to that of Fig. 16, illustrating the conductive cutting hoop of the invention actuated to a drawn severing position;

Fig. 18 is a perspective view similar to that of Fig. 1, illustrating a fourth preferred embodiment of the inventive tissue sampling instrument;

5 Fig. 19 is a perspective view of the distal or business end of the embodiment illustrated in Fig. 18;

Fig. 20 is a perspective view similar to that of Fig. 1, illustrating a fifth preferred embodiment of the inventive tissue sampling device;

10 Fig. 21 is a perspective view of the distal end portion of the embodiment illustrated in Fig. 20, wherein the distal end is preformed to a predetermined shape;

15 Fig. 22 is a perspective view similar to Fig. 21, illustrating the retraction of an inner cannula and subsequent relaxation of the distal end to its predetermined shape;

Fig. 23 is a perspective view similar to that of Fig. 1, illustrating a sixth preferred embodiment of the inventive tissue sampling device;

20 Figs. 24-27 are perspective views of the distal end portion of the Fig. 23 embodiment, in various operating positions;

25 Fig. 28 is a perspective view similar to that of Fig. 23, illustrating the tissue sampling instrument in a pre-sampling condition;

Fig. 29 is a perspective view of a stand-alone sensing probe which may be used in connection with the embodiment of Fig. 28;

30 Figs. 30, 30a, and 30b are perspective views of a multi-vision probe which may be used in connection with the embodiment of Fig. 28;

Fig. 31 is a side view of endoscopic shears which may be utilized in connection with the embodiment of Fig. 28;

Fig. 32 is an end view of the endoscopic shears illustrated in Fig. 31;

Fig. 33 is a perspective view of a seventh preferred embodiment of the inventive tissue sampling instrument, which incorporates a mechanical tissue removal system; and

Fig. 34 is a cross-sectional view of the tissue acquisition device illustrated in Fig. 33.

10 Description of the Invention

Referring now more particularly to Figures 1-8, a first preferred embodiment of the invention is shown. The inventive tissue sampling probe 10 comprises a tube 12 having a primary lumen 14 and a secondary lumen 16. Extending axially through the secondary lumen 16 is a support stem 18, preferably comprised of an electrically conductive metallic wire, which is joined at its distal end to a conductive cutting loop 20.

The tube 12 is connected, at its proximal end, to a source of vacuum 13, which is adapted for selectively drawing a vacuum through the primary lumen 14. The tube 12 is preferably fabricated of a non-conductive radiolucent or radiodense biocompatible material, such as plastic or epoxy, and preferably has a round cross-section, though other tube shapes may be used as well. The material may also be electrically conductive if its entire outside surface area is covered with an electrically insulative material (not shown).

As shown in Figs. 3 and 4, the conductive cutting loop 20 may be pivoted rotationally in a direction transverse to the longitudinal axis 22 of the tube 12, from a rightmost position (Fig.3) to a leftmost position (Fig.4). This pivoting action is created by rotation of the support stem 18 using an actuator 24 disposed at a proximal end of the inventive tissue sampling probe 10 (Fig. 1). The actuator 24 preferably comprises a housing 26, a fixed handle 28, a loop advancement slide knob 29, a trigger 30, a vacuum override switch 31, and an electrosurgical energy/vacuum actuation switch 32. The housing 26 encloses a spring mechanism (not shown) for joining the trigger 30 and the support stem 18 so that when the

trigger 30 is squeezed in a conventional manner, against the bias of the spring mechanism, the support stem 18 is rotated to pivot the conductive cutting loop 20 to the position shown in Figure 3. When the trigger 30 is opened in the direction opposite of the squeezing direction, against the bias of the spring mechanism, the support stem 18 is rotated to pivot the conductive loop 20 to the position shown in Figure 4. Any other type of desired conventional actuator may be used as well, including manual, motor-driven, and electronically-driven mechanisms.

An important aspect of the invention is the use of an electrocautery generator 33 (Figure 1). The electrical energy from the electrocautery generator is conducted along electrical line 33a to the support stem 18 and from there to the conductive cutting loop 20 of the apparatus shown in Figure 1. Additionally, the source of vacuum 13 is also employed to selectively draw a vacuum through a vacuum line 13a and along the tissue receiving lumen 14 formed by the tube 12.

Therefore, in operation, with respect to the embodiment of Figure 1, the electrocautery generator is activated using the actuation switch 32 to electrically activate the conductive cutting loop 20. When the actuation switch 32 is depressed, the vacuum source is simultaneously activated to draw a vacuum through the lumen 14. Once these systems are operational, the tube 12 is advanced through tissue to obtain the desired tissue sample. In the preferred embodiment, depth marks 34 are disposed axially along the exterior surface of the tube 12 in order to assist the physician in determining when the tube 12 has been advanced to the desired position.

In its preferred operational mode, the energized conductive cutting loop 20 functions to cut a tissue sample having approximately the same diameter or cross-sectional shape as that of the tube 12. Surprisingly, the inventors have found that the combination of an activated electrocautery cutting element and the drawing of a vacuum at the cutting site proximally through the tissue receiving lumen 14 improves and expedites the tissue capture process, to an unexpected degree. While soft tissues typically tend to move away from a severing instrument, such as a knife blade, the vacuum tends to counteract this movement, resulting in a startlingly improved cutting process.

Once a sample of adequate length has been secured, the conductive cutting loop 20 is electrically actuated for cutting and mechanically actuated to rotatably

pivot both rightwardly and leftwardly, as shown in Figures 3 and 4, using the trigger actuator 24. This pivoting action functions to sever the distal end of the tissue sample (not shown) from the remaining body tissue, thereby completing the capture process. Furthermore, as illustrated in Figure 1, a tissue reservoir or vacuum trap 57 may be employed in the vacuum line proximally of the sampling probe 10 for receiving and storing tissue samples drawn proximally through the sampling device body by the vacuum source 13.

An important aspect of the invention, critical to the functionality of the instrument shown in Fig. 1, is that the annular space within the lumen 16 surrounding the support stem 18 serves as a vent port when the tissue sample is drawn out of the body by the negative pressure created by the vacuum source 13, thereby repressurizing the space in the tube lumen 14 distal of the tissue sample. Without this repressurization capability, trouble-free operation in obtaining the desired tissue samples is unlikely because of pressure gradient variations. It should be noted, also, that actuation of the vacuum override switch 31 permits operation of the device without the application of vacuum pressure, if desired.

As illustrated in Figs. 5-6, the support stem 18 may be actuated axially as well as rotationally, between a proximal position, as shown in Fig. 5, wherein the conductive cutting loop 20 is retracted, and a distal position, as shown in Fig. 6, wherein the conductive cutting loop is extended. The loop advancement slide knob 29, which is fixedly attached to the support stem 18 by means of a conventional connective element enclosed within the housing 26, is utilized to axially advance and retract the cutting loop. Advancing the cutting loop 20 axially provides an alternate means of cutting tissue in an axial direction without requiring the entire sampling probe 10 to move axially as well.

An advantageous optional feature of the present invention is illustrated in Figures 7 and 8, wherein the support stem 18 has been preformed to permit movement of the cutting loop 20 in a non-straight direction as it is advanced into the tissue, as shown in Figure 8. Such a feature may be important if the tissue to be sampled is disposed to the side of the entry path for the device 10, such as, for example, when a lesion to be sampled is disposed in a side wall of a body cavity or conduit.

Figures 9-10 illustrate a particular embodiment of the invention which may utilize a modified version of the instrument shown in Figures 1-8, or which may alternatively utilize other similar devices such as the embodiments shown in Figures 13-28 and described infra. As discussed supra with respect to the embodiment shown in Figures 7-8, it is often the case that it is desirable to sample selected areas of a cavity wall from within the cavity, and for such a purpose a probe capable of non-axial movement, and preferably having flexible characteristics, is necessary. In one preferred implementation, an automatic core biopsy device 35 of the type disclosed in U.S. Patent Application Serial No. 08/217,246, filed on March 24, 1994, and Application Serial No. 08/386,941, filed on February 10, 1995, both of which are assigned to the assignee of the present application, and are herein expressly incorporated by reference, is employed. Such a device is presently commercially available from Biopsys Medical, Inc., of Irvine, California, the assignee of the present application, under the trademark MAMMOTOME. The automatic biopsy device 35 comprises a hollow outer piercing needle 36 having a pointed tip 37 and a tissue receiving notch 38. A proximal tissue cassette housing 40 includes a cassette receiving aperture 42 and a vacuum port 44. As discussed in the prior Patent Applications Serial Nos. 08/217,246 and 08/386,941, the biopsy device 35 is adapted to enter the patient's body using commercially available imaging guidance systems commonly used in the medical field for accurate positioning of a variety of medical devices with respect to a patient and with respect to a lesion within a patient. For example, a stereotactic motorized biopsy needle positioning system, such as that disclosed in U.S. Patent No. 5,240,011, issued on August 31, 1993, to Michael Assa, which is expressly incorporated herein by reference, may be used. The suspect lesion within the tissue to be sampled is targeted according to the instructions provided with the stereotactic guidance system. The stereotactic guidance system enables an operator to advance the pointed tip 37 until it is adjacent to the specific tissue region to be sampled.

Alternatively, other guidance systems may be used in conjunction with the inventive device, such as ultrasound, radiolabelling with detector, or localization wire.

A flexible sampling device 46 having a distal end 48 may be percutaneously delivered to the site of a lesion to be sampled by inserting it

through the automatic core biopsy device 35. Preferably, the sampling device 46 is received by the cassette receiving aperture 42 and extends through the lumen of the hollow outer piercing needle 36, exiting into a body cavity 50 (Figs. 11 and 12) through the tissue receiving notch 38. Because of its flexibility and torqueability, the sampling device 46 is capable of sampling any selected area of the cavity wall. To do so, as illustrated in Figure 11, the end of the sampling device 46 extends into the cavity wall 52 to a depth predetermined by the operator to be appropriate. The distal end of the sampling device 46, or "business end", may be constructed in accordance with the principles illustrated in Figure 1, or, alternatively, any of the other embodiments illustrated in Figures 13-28, and is preferably configured to ensure that the effective diameter of the incision is less than about 7 mm, in order to hopefully avoid the need for stitches. Larger diameter sampling devices are certainly feasible, however. Thus, the tube 12 of the device illustrated in Figure 1 may be constructed of a substantially rigid electrically conductive biocompatible material, to create a substantially rigid probe device, or alternatively, it may be constructed of a flexible biocompatible material like that shown in Figures 10 and 11 (flexible sampling device 46).

As illustrated in Figures 13 and 14, the lumen 14 may be configured to accept a plurality of sequentially obtained tissue samples during a single medical procedure, with only a single entry and exit of the device into and out of the patient's body. Optionally, a movable stop plunger 58 having a vacuum lumen 60 extending therethrough may be employed, wherein the stop plunger is arranged to be progressively moved proximally as specimens are obtained, to permit space for the additional specimens while at the same time prohibiting the specimens from being drawn through the tube 12 to the vacuum source. Additionally, it may be desirable to coat the inner surface of the tube 12 with a hydrophilic or slick coating in order to facilitate transport of the tissue sample. A stop plunger lever 61 (Fig. 13), disposed on a proximal portion of the housing 26, is axially slidable within a slide channel 62 to axially move the stop plunger 58.

Many other embodiments may be employed other than the embodiment illustrated in Figures 1 and 13. For example, a modified embodiment is illustrated in Figures 15-17, wherein all elements corresponding to those of the embodiment of Figure 1 are designated by like reference numerals, succeeded by the letter "a". In

5 this embodiment, the conductive cutting loop 20a is comprised of a pair of wires 120 and 220, both of which extend proximally through the secondary lumen 16a in the form of support stems 118 and 218, respectively. As in the prior embodiment, the wires 120 and 220 are capable of conducting electrical energy for electrocautery purposes. Figure 16 illustrates the wires 120 and 220 in their rest position, while Figure 17 illustrates the wires after the support stems 118 and 218 have been pulled proximally by pulling a slide lever 63 in a proximal direction, which slide lever 63 is operatively connected to the support stems 118 and 218. Pulling the support stems 118 and 218 proximally causes the wires to close the end of the tube 12a and thereby sever the distal end of the tissue sample contained within the tube lumen 14a, in a manner similar to that of the loop 20 in the Figure 1 embodiment. An important difference between the Figure 1 and Figures 15-17 embodiments is that the drawing of the two wires 120 and 220 to a closed position functions to sever only the distal end of the tissue sample without cutting and thereby injuring surrounding tissue, unlike the conductive cutting loop 20 of Figure 1, which, as shown in Figures 3 and 4, substantially impacts surrounding tissue during the rotational severing process.

15 Still another embodiment of the inventive apparatus is illustrated in Figures 18 and 19, wherein like elements to those of previous embodiments are designated by like reference numerals, succeeded by the letter "c". In this embodiment, a partial wire hoop 20c is utilized, which is shown in solid line in its rest position, and in phantom in its actuated position. To sever the distal end of the tissue sample, the partial hoop 20c is rotated from the rest position to the actuated position, by rotating the support stem 18c using an actuator 24c, which may be identical to actuator 24 illustrated in Figure 13, if desired, following which the body tube 12c is rotated by 180 degrees to complete the tissue severing task. In this embodiment, unlike the embodiment of Fig. 1, for example, the hoop 20c does not function as the axial cutting element as the instrument is advanced into the target tissue. Rather, the tube 12c is electrically conductive in this embodiment, and, in order to ensure safe handling of the instrument, is therefore covered by an insulative sleeve 64 along its entire length (Fig. 19), except at its distal end. The uncovered distal end 65 of the tube 12c is therefore electrically charged and

exposed, so that the distal end 65 functions as an electrosurgical axial cutting element as the instrument is advanced through the tissue.

Yet another embodiment of the inventive apparatus is shown in Figures 20-22, wherein like elements to those of previous embodiments are designated by like reference numerals, succeeded by the letter "d". In Figure 20, the conductive tubing body 12d is illustrated, wherein a circumferential slit 66 has been partially cut through the tube 12d near its distal end. A band of tubing material 67 disposed distally of the slit 66 is then bent inwardly and stress relieved in the position shown in Figure 22. Following this, as illustrated in Figure 21, an inner coaxial tube 68 is inserted into the tubing body 12d to force the material band 67 open. At this point, the instrument 10d is ready to use. When the tube 12d has been advanced into a patient's body to obtain a tissue sample, the inner tube 68 is removed to cause the band of material 67 to snap inwardly to its natural stress relieved position, as shown in Figure 22. Since the tubing 12d, and therefore the material band 67 are electrically energized, the motion of the band of material 67 inwardly functions to partially cut off the distal end of the tissue sample. The tube 12d is then rotated 180 degrees to completely sever the tissue sample.

Figures 23-27 illustrate still another embodiment of the inventive device, wherein like elements to those of previous devices are designated with like reference numerals, succeeded by the letter "e". In this embodiment, a wire loop 20e is adapted to pivot from one side of the tube 12e (Figure 24) to the other side of the tube 12e (Figure 27). As with the previous embodiments, rotation of the wire loop 20e, which is energized by the electrocautery generator (not shown), severs the distal end of the tissue sample being captured, which capture is assisted by the simultaneous application of a suction to the proximal end of the lumen 14e. Again, the design of the wire loop 20e of this embodiment advantageously minimizes damage to tissue surrounding the tissue to be captured.

In the Fig. 23 embodiment, the housing 26e is shown cut away, so that the actuating mechanism 69 for the hoop 20e is visible. For this preferred actuating mechanism, an upper portion 70 of the bidirectional trigger 30e comprises a pinion, having teeth which engage a rack 71, which in turn is connected to the support stem 18e to drivingly rotate the hoop 20e in either of two directions. Optionally, this actuating mechanism 69 may be utilized in any of the illustrated embodiments,

if desired. On the proximal end of the housing 26e, a pair of fittings are disposed for attachment to corresponding control lines 86 and 88, respectively (illustrated in Fig. 28).

5 A particularly advantageous aspect of the invention is its ability to be used in connection with sensing probes for identifying and locating desired tissue to be sampled. For example, ultrasound probes or radiation detecting (Geiger) probes may be employed, such as those disclosed in U.S. Patent Nos. 4,959,547, 5,036,201, 5,119,818, 5,148,040, 5,170,055, and 5,246,005, which are assigned to Care Wise Medical Products Corporation of Morgan Hill, California, and are herein
10 expressly incorporated by reference. Referring particularly to Figures 28-30, wherein like elements to those of previous devices are designated with like reference numerals, succeeded by the letter "g", a tissue sampling probe, or soft tissue acquisition device 10g is illustrated, having a tube 12g, a primary lumen 14g, a secondary lumen 16g, a support stem 18g, and a conductive cutting loop 20g.
15 The cutting loop 20g may comprise any of the types of cutting loops disclosed in the previous embodiments, as desired. A handle 24g is preferably joined to a proximal end of the tube 12g, and includes a trigger 30g and a through hole 78, which is configured to receive a sensing probe 80 or 82 (Figures 29 and 30). The handle may be manually held, or may alternatively be held by a mechanical arm or
20 fixed to a stereotactic platform or the like.

A stand alone sensing probe 80 is illustrated in Figure 30, which may comprise either an ultrasonic probe or a geiger probe, both of which are conventionally known in the medical diagnostic arts. The probe 80 is specifically
25 configured to mate into the through hole 78 of the soft tissue acquisition device 10g. Electronic control lines 84 extend from a proximal end of the probe 80 to appropriate control units, for receiving and processing information obtained by the probe.

Alternatively, a multi-vision probe, such as the probe 82 illustrated in Figure 30, may be utilized. This type of probe is capable of functioning both as an
30 ultrasonic probe and as a geiger probe, and has two sets of control lines 86 and 88 for communicating with ultrasonic and geiger electronic control units, respectively.

In operation, a lesion (tissue) 90 to be sampled (Figure 28) is located using a multi-vision probe 82 or a combination of stand-alone probes 80, which are

disposed in the soft tissue acquisition device 10g. The geiger portion of the probe provides an X-Y location on the surface of the tissue to be sampled, while the ultrasonic portion provides depth information as well as X-Y location information. Then, the soft tissue acquisition device 10g is held in position, while the sensing probe(s) is (are) removed. Following location of the lesion 90, scissors 92 (Figure 31) having depth marks 94 and blades 96, 98, may be used, if necessary, through the lumen 14g to dissect distally to a position within the tissue just proximal to the lesion 90 of interest. Then, the scissors 92 are removed from the lumen 14g, and the tissue acquisition device 10g is electrically energized and advanced to the pre-determined depth. At this juncture, the end cutting loop 20g is utilized in a manner similar to that discussed in connection with previously disclosed embodiments to sever the distal end of the tissue specimen, following which suction is activated, using vacuum switch 31g, to transport the specimen proximally through the lumen 14g.

Referring now to Figure 33 and 34, another embodiment of the inventive soft tissue acquisition device is provided, wherein like elements to those of previous devices are designated with like reference numerals, succeeded by the letter "i".

Although the use of negative pressure to withdraw the tissue specimens is preferred, the invention is broad enough to include other approaches for ensuring prompt and efficient retrieval of intact specimens. For example, as illustrated in Figures 33 and 34, a mechanical grasper 112 having a shaft 114 extending through a rear port 116 configured for working instruments, and the lumen 14i, is employed to grasp tissue using distal jaws 118, which are openable and closable by means of handles 120. In this embodiment, the trigger 30i may be pulled to simultaneously actuate the vacuum and electrosurgical generator, thereby causing the tissue sample to be severed, as described with respect to the aforementioned embodiments. Then, simultaneously with the severing process, the graspers 112 may be used to "grab" the tissue sample with the jaws 118, and to pull the sample proximally through the lumen 14i. Optionally, a "vacuum only" button 122 and an "electrosurgical power only" button 124 are disposed on the housing 26i so that the physician may elect to cut out either vacuum or electrosurgical power when pulling the trigger. The vacuum line is attached to a vacuum fitting 126 and the electrosurgical power line is attached to an electrosurgical fitting 128, both of which are disposed on the

housing 26i. A particular advantage of this embodiment, in certain applications, is that there is no electrosurgical cutting hoop disposed distally of the cutting end of the tube 12i, so the instrument is ideally suited for retrieving samples from tissues which have been dissected away from the "parent" tissue, yet are still in the body.

5 Such is often the case in laparoscopic surgery applications.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A tissue sampling apparatus, comprising:
a tubular body having a primary lumen for receiving a tissue sample, and
having a distal end and a proximal end;
a non-rotating electrosurgical cutting element disposed at the distal end of
5 the tubular body; and
a means for drawing tissue to be sampled into the primary lumen, whereby
the electrosurgical cutting element cuts said tissue to capture an intact tissue sample
core within said lumen.
2. The tissue sampling apparatus recited in Claim 1, wherein the
electrosurgical cutting element comprises a wire disposed distally of the distal end
of the tubular body.
3. The tissue sampling apparatus recited in Claim 2, and further
comprising a support stem attached to said wire and disposed proximally thereof for
supporting and controlling said wire, and a secondary lumen for receiving said
support stem.
4. The tissue sampling apparatus recited in Claim 3, wherein said
means for drawing tissue comprises a source of vacuum pressure for drawing a
vacuum through the primary lumen; the vacuum pressure in the primary lumen
drawing tissue to be sampled into the primary lumen and the electrosurgical cutting
5 element cutting said tissue to capture an intact tissue sample core within said
primary lumen.
5. The tissue sampling apparatus recited in Claim 4, wherein annular
space surrounding said support stem within said secondary lumen functions as a
vent port, drawing air at ambient pressure distally therethrough to repressurize
regions in said primary lumen distal to the tissue sample being drawn proximally
5 through said primary lumen; said repressurization functioning to assist transit of
said sample proximally through the primary lumen.

6. The tissue sampling apparatus recited in Claim 2, wherein the tubular body is comprised of a non-electrically conductive material.

7. The tissue sampling apparatus recited in Claim 2, wherein the wire comprises a single substantially circular wire which is rotationally pivotable from side-to-side to sever a distal end of the tissue sample, thereby completely severing the tissue sample from surrounding tissue.

8. The tissue sampling apparatus recited in Claim 2, wherein the wire comprises a pair of wires which together are actuatable from a rest position to a severing position, the pair of wires together forming a substantially circular cutting element disposed about the distal edge of the tubular body in the rest position, and the pair of wires being drawn together across the cross-sectional area of the distal end of the tubular body in the severing position, while being electrically energized, the drawing motion of the wires across the cross-sectional area functioning to sever a distal end of the tissue sample, thereby completely severing the tissue sample from surrounding tissue.

9. The tissue sampling apparatus recited in Claim 2, wherein the wire comprises a single wire which is actuatable from a rest position to a severing position, the wire forming a substantially circular cutting element disposed about the distal edge of the tubular body in the rest position, and the wire being drawn across the cross-sectional area of the distal end of the tubular body while being electrically energized in the severing position, the drawing motion of the wire across the cross-sectional area functioning to sever a distal end of the tissue sample, thereby completely severing the tissue sample from surrounding tissue.

10. The tissue sampling apparatus recited in Claim 2, wherein the wire comprises a single wire which is actuatable from a rest position to a severing position, the wire forming a semicircular cutting element disposed about a portion of the distal edge of the tubular body in the rest position, and the wire being drawn across the cross-sectional area of the distal end of the tubular body while being

electrically energized in the severing position, the drawing motion of the wire across the cross-sectional area functioning to sever a portion of the distal end of the tissue sample.

11. The tissue sampling apparatus recited in Claim 2, wherein the wire comprises a single wire which is actuatable from a rest position to a severing position, the wire forming a semicircular cutting element disposed about a portion of the distal edge of the tubular body in the rest position, and the wire being drawn
5 across the cross-sectional area of the distal end of the tubular body while being electrically energized in the severing position, to a position about an opposing portion of the distal edge of the tubular body from the portion of the distal edge about which the wire is disposed in the rest position, wherein the wire has a pair of ends which are each fixedly attached to opposing sides of the tubular body distal
10 edge, the drawing motion of the wire across the cross-sectional area functioning to sever the distal end of the tissue sample.

12. The tissue sampling apparatus as recited in Claim 1, wherein a distal portion of the tubular body includes a slit extending part of the way through the thickness of the tube wall, the slit creating a flexible band of material between the slit and the distal end of the tubular body, the flexible band of material being
5 predisposed to rest in a partially collapsed position across the cross-sectional area of the tubular body, the apparatus further comprising an inner coaxial tube adapted to be inserted into the lumen of the tubular body to thereby push the material band into a circumferential configuration substantially coincident with the remainder of the tubular body, the tubular body being electrically conductive to conduct
10 electrical energy from an electrocautery generator to the flexible band of material which thereby comprises said electrosurgical element, wherein when the inner coaxial tube is removed from the tubular body lumen, the electrically energized flexible band of material collapses to its rest position across the cross-sectional area of the tubular body, the collapsing motion of the band of material functioning to
15 sever the distal end of a tissue sample.

13. The tissue sampling apparatus as recited in Claim 1, wherein said tubular body lumen is adapted to accommodate a plurality of tissue samples.

14. The tissue sampling apparatus as recited in Claim 13, and further comprising a movable stop plunger disposed at the proximal end of the tubular body lumen, said movable stop plunger preventing the tissue samples from being drawn proximally to the vacuum pressure source, and being movable in a proximal direction as additional tissue samples are captured in order to expand the lumen space available to accommodate the tissue samples.

15. The tissue sampling apparatus as recited in Claim 3, wherein the support stem is movable proximally to retract the wire cutting element in a proximal direction, and is movable distally to extend the wire cutting element in a distal direction.

16. The tissue sampling apparatus as recited in Claim 15, wherein the support stem is preformed to allow movement of the wire cutting element in a non-linear direction as it is extended distally.

17. The tissue sampling apparatus as recited in Claim 1, wherein the tubular body is flexible and steerable in order to obtain tissue samples from any desired location on the wall of a tissue cavity, and the apparatus is adapted for delivery to a desired tissue location percutaneously.

18. The tissue sampling apparatus as recited in Claim 17, and further comprising a percutaneous biopsy instrument having a hollow outer piercing needle which is adapted for entry into a patient's body, the hollow outer piercing needle including a lumen extending along its length, wherein the flexible tubular body is adapted for insertion into the patient's body through said hollow outer piercing needle lumen.

19. The tissue sampling apparatus as recited in Claim 2, wherein the distal end of the tubular body comprises said electrosurgical cutting element, the

tubular body being constructed of an electrically conductive material and being further surrounded by an insulative jacket along its entire length except at the distal cutting end.

20. The tissue sampling apparatus as recited in Claim 3, and further comprising a mechanical actuator for moving said wire through said support stem.

21. The tissue sampling apparatus as recited in Claim 1, wherein said means for drawing tissue comprises a source of vacuum pressure for drawing a vacuum through the primary lumen; the vacuum pressure in the primary lumen drawing tissue to be sampled into the primary lumen and the electrosurgical cutting
5 element cutting said tissue to capture an intact tissue sample core within said primary lumen.

22. The tissue sampling apparatus as recited in Claim 21, wherein said apparatus further comprises a housing portion, the housing portion including a first switch for simultaneously activating the source of vacuum pressure and an electrocautery generator for providing electrical current to said electrosurgical
5 cutting element, a second switch for activating only the source of vacuum pressure, and a third switch for activating only the electrocautery generator.

23. The tissue sampling apparatus as recited in Claim 21, and further comprising a tissue reservoir disposed proximally of said tubular body.

24. The tissue sampling apparatus as recited in Claim 23, wherein said tissue reservoir is disposed in a vacuum pressure line between the tubular body and the source of vacuum pressure.

25. The tissue sampling apparatus as recited in Claim 21, and further comprising a vacuum override switch for selectively cutting off the source of vacuum pressure.

26. The tissue sampling apparatus as recited in Claim 1, and further comprising a coating on the interior surface of the tubular body to facilitate transport of tissue samples therethrough.

27. The tissue sampling apparatus as recited in Claim 1, and further comprising depth marks on said tubular body to facilitate positioning of the apparatus in a patient's body.

28. The tissue sampling apparatus as recited in Claim 1, wherein said tubular body is adapted to accommodate insertion of a sensing probe through the primary lumen thereof.

29. The tissue sampling apparatus as recited in Claim 28, wherein said sensing probe comprises a radiation detecting probe.

30. The tissue sampling apparatus as recited in Claim 28, wherein said sensing probe comprises an ultrasound probe.

31. The tissue sampling apparatus as recited in Claim 28, wherein said sensing probe comprises a multivision probe.

32. The tissue sampling apparatus as recited in Claim 28, wherein said apparatus is adapted to accommodate a scissors through the primary lumen after the sensing probe has been removed therefrom, said scissors functioning to dissect distally to a position just proximal to a lesion of interest.

33. The tissue sampling apparatus as recited in Claim 1, wherein said means for drawing tissue comprises a mechanical grasper having openable jaws which are adapted to extend through the primary lumen of said tubular body.

34. A method of capturing a body tissue sample using a tissue sampling apparatus comprising a tubular body having a lumen extending therethrough, a distal end, an electrosurgical cutting element disposed distally of the distal end of

- the tubular body, an actuator for moving the cutting element, and an electrocautery generator, the method comprising:
- 5 activating the electrocautery generator to energize the electrosurgical cutting element;
- advancing the tubular body through a tissue portion a desired distance so that the energized electrosurgical cutting element cuts a tissue sample core as the
- 10 tissue sample enters the lumen; and
- actuating the electrically energized cutting element so that it moves across at least a portion of the cross-sectional area of the tissue sample core at its distal end, thereby severing the distal end to capture the tissue sample core in a substantially intact condition within the tubular body lumen.

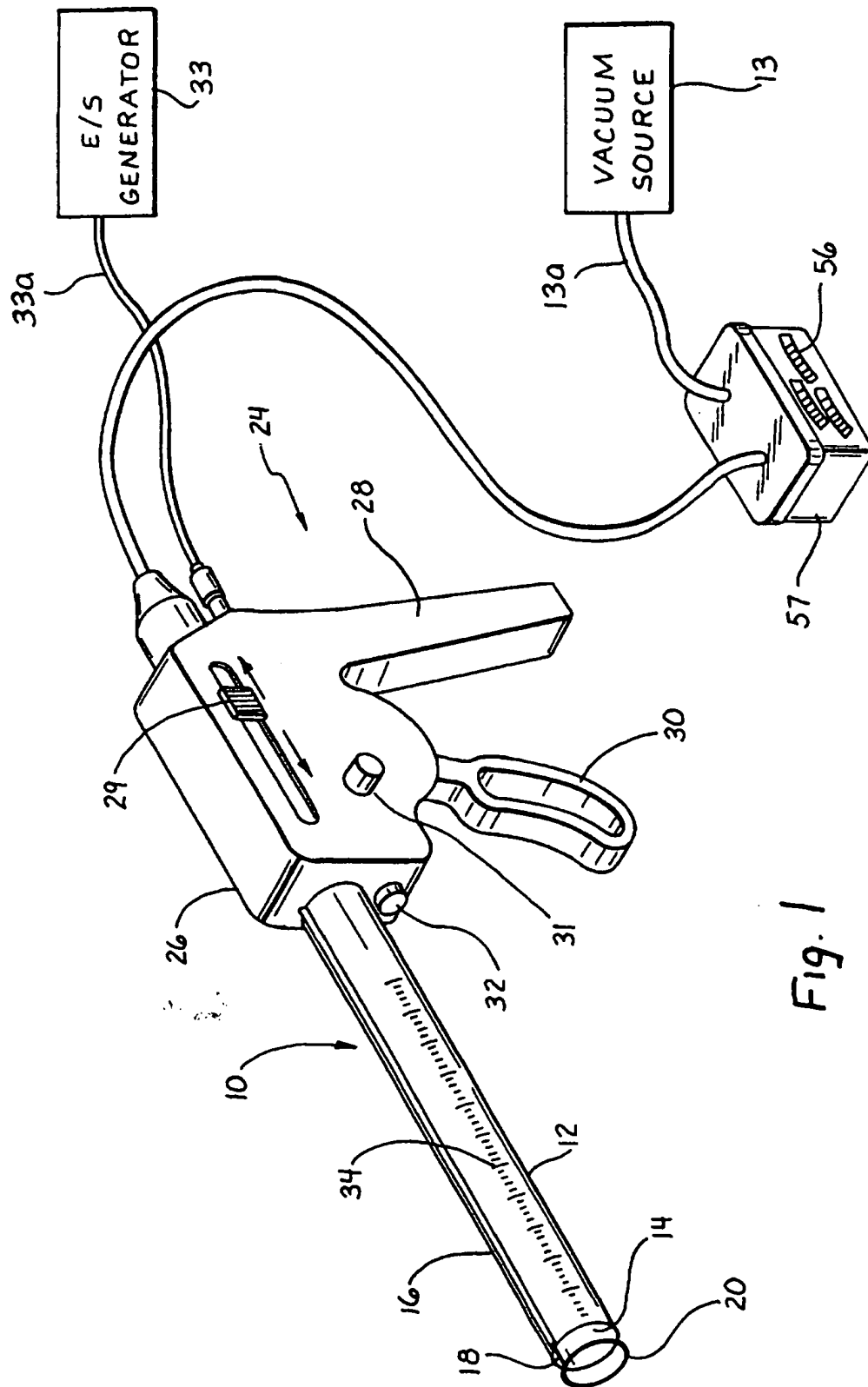
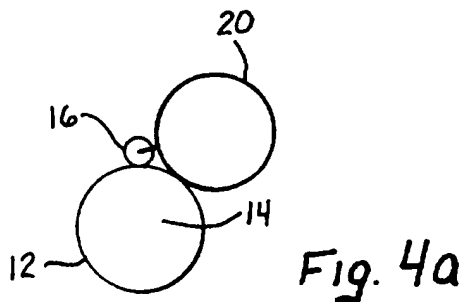
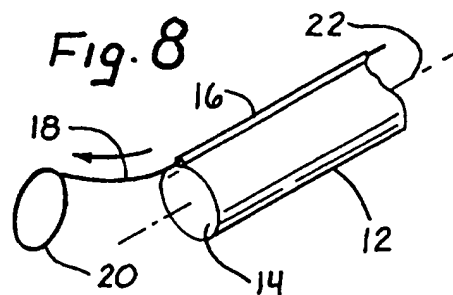
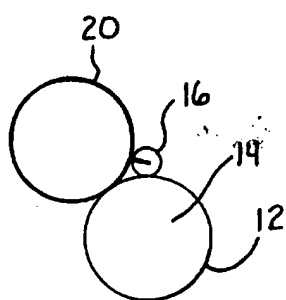
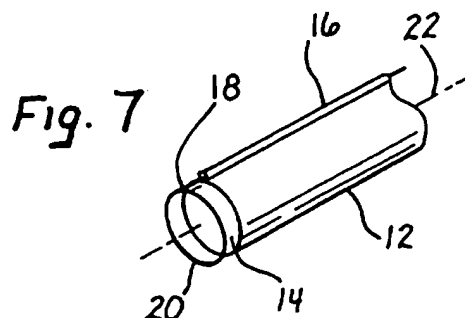
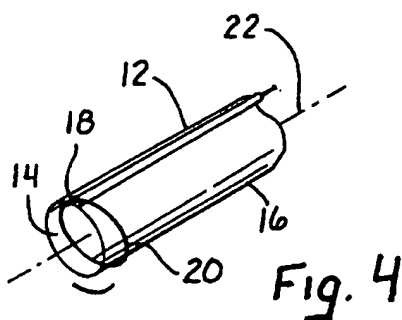
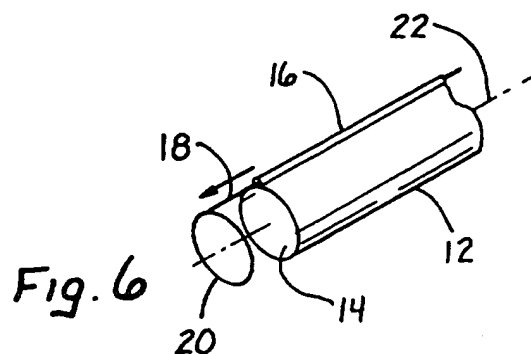
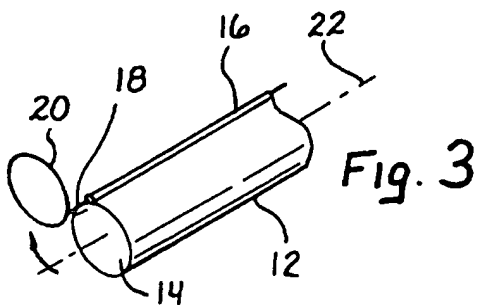
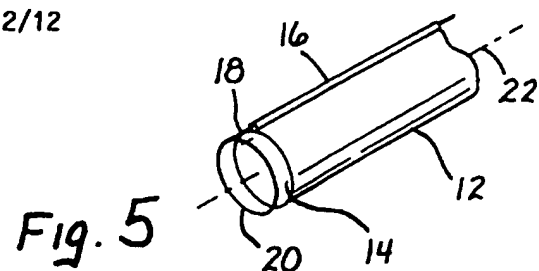
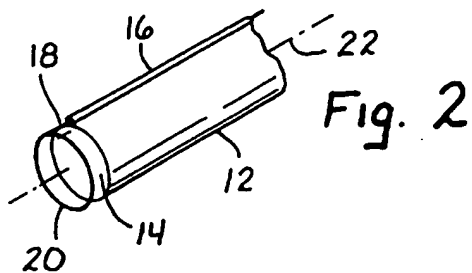


Fig. 1



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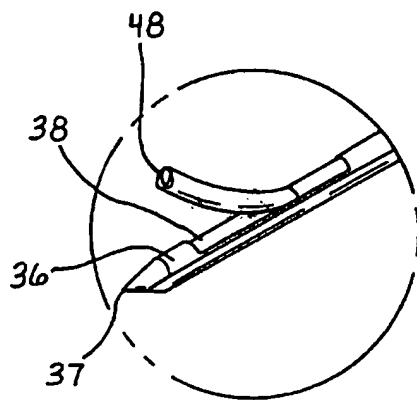
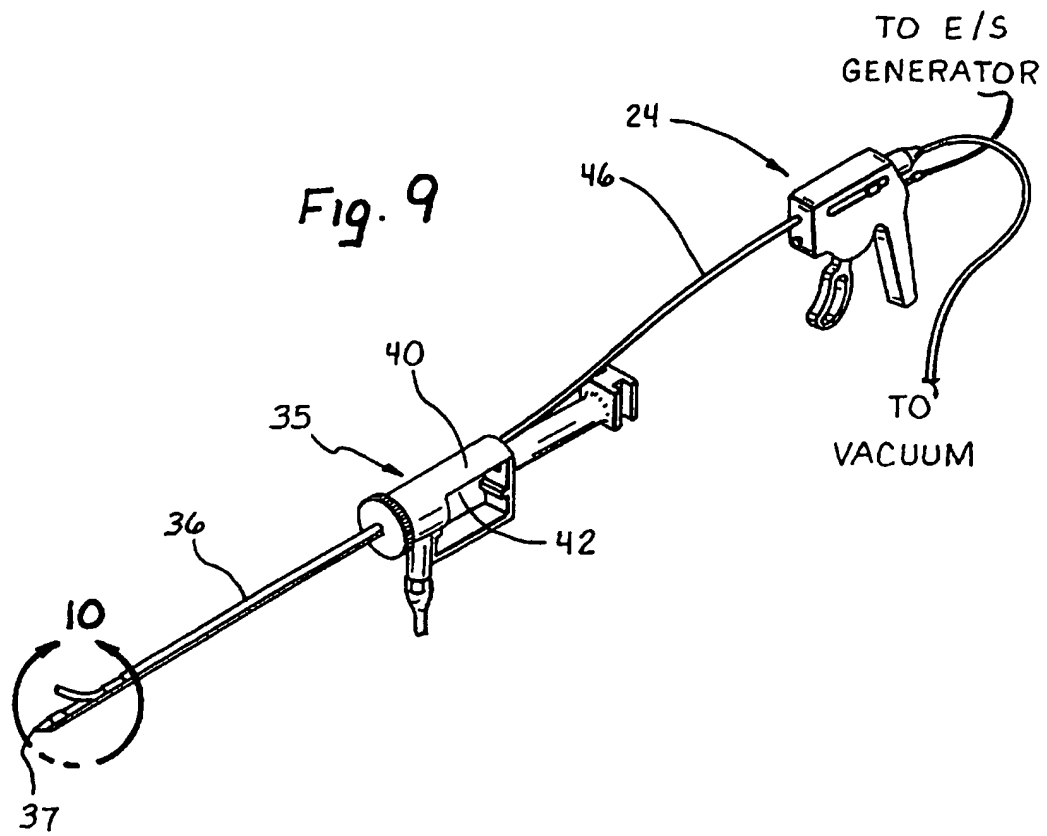


Fig. 10

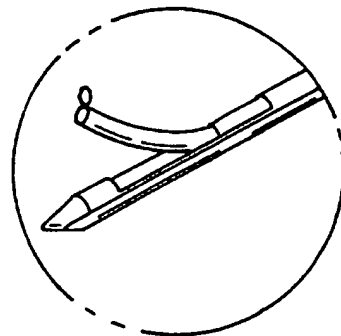


Fig. 10a

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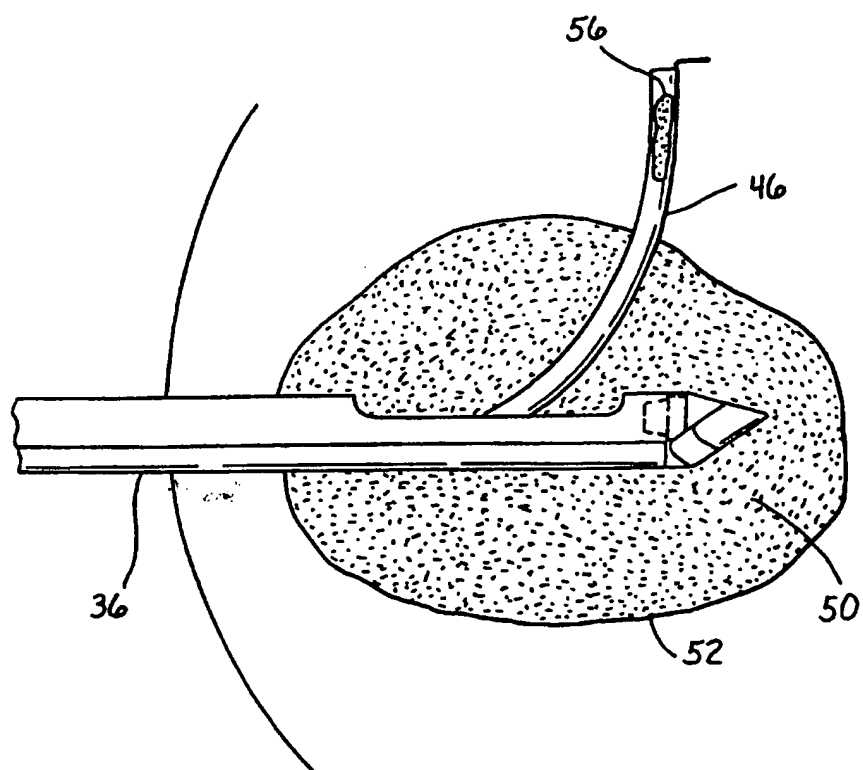
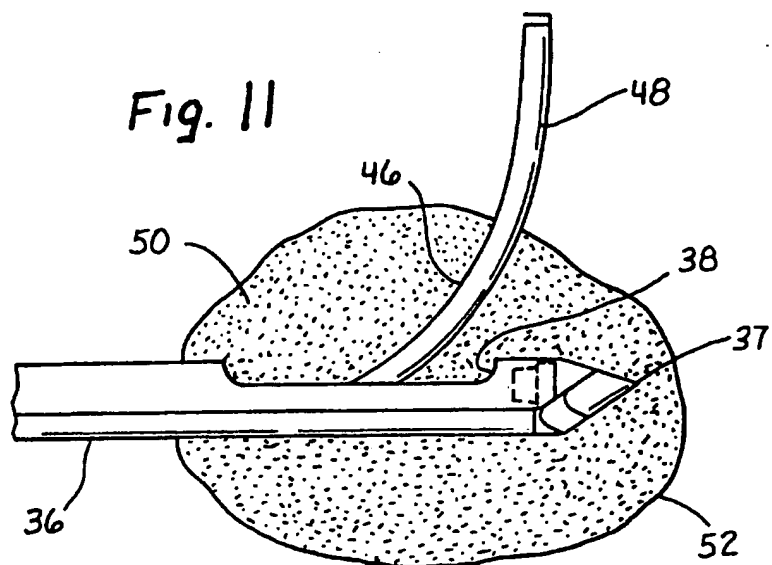
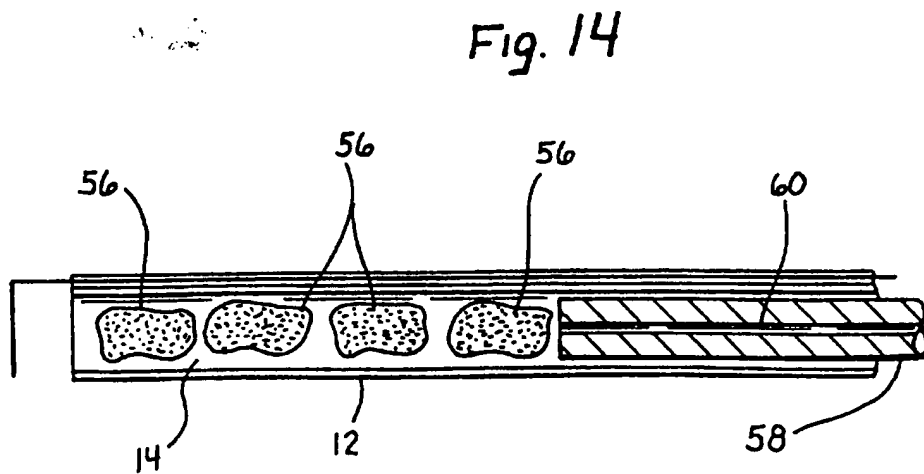
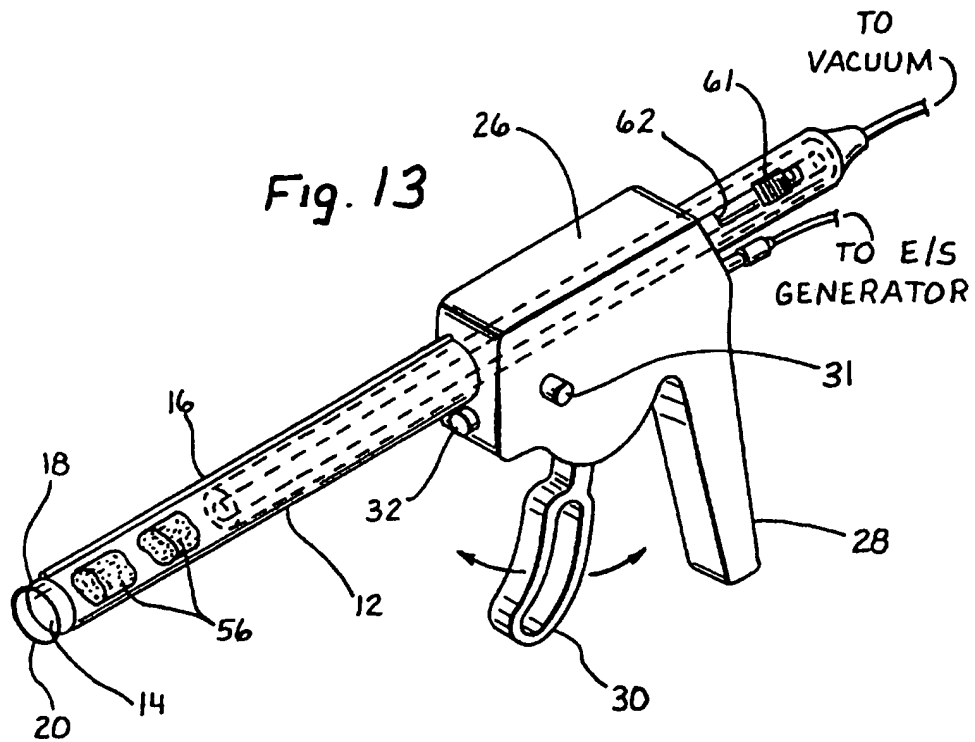
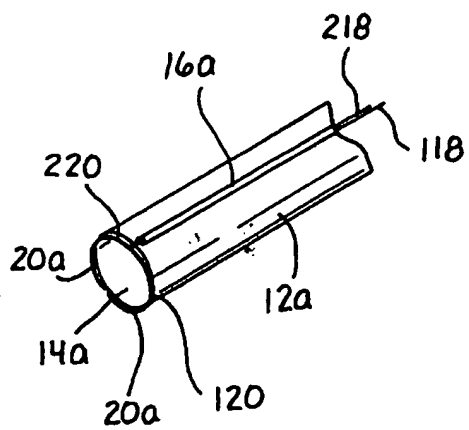
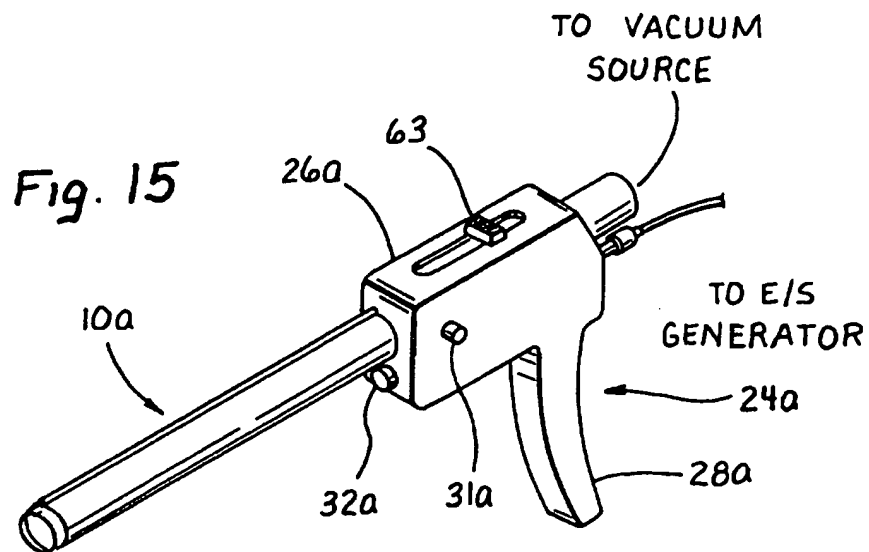
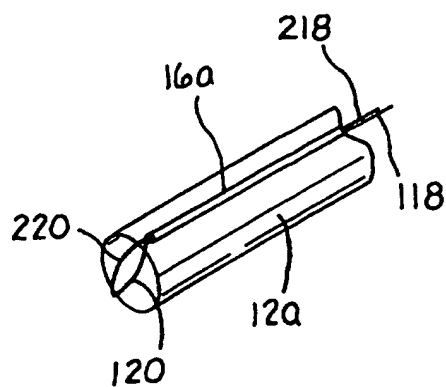


Fig. 12

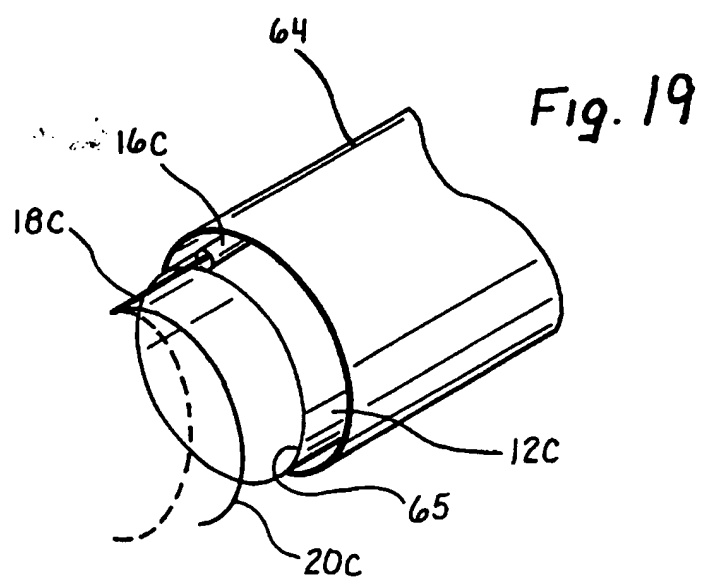
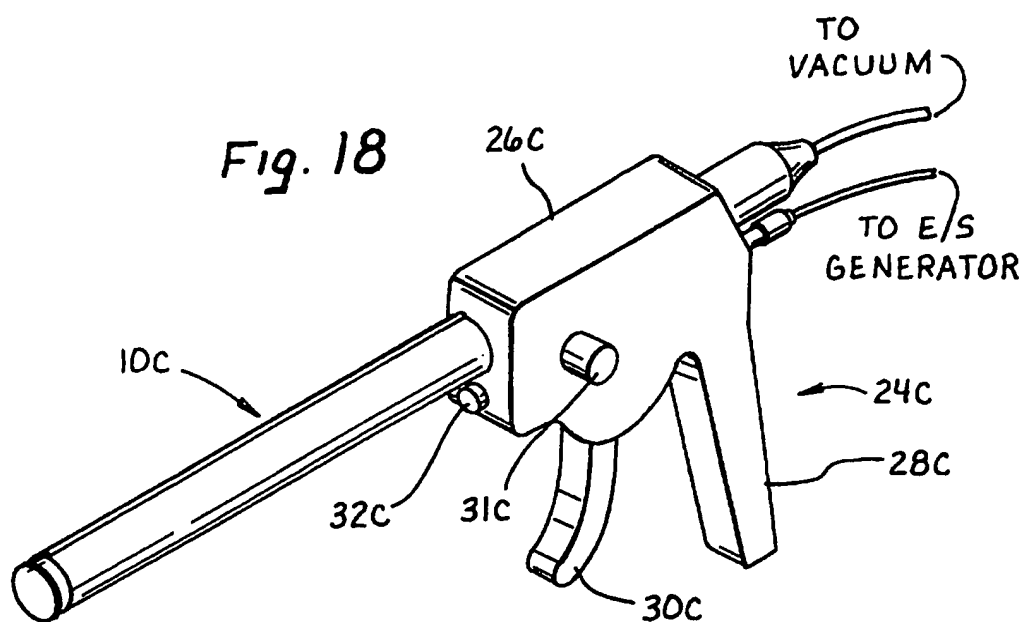
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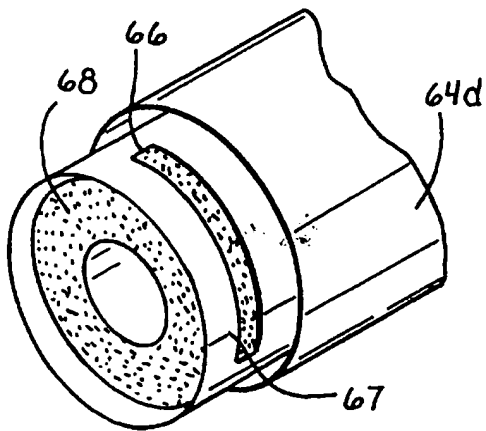
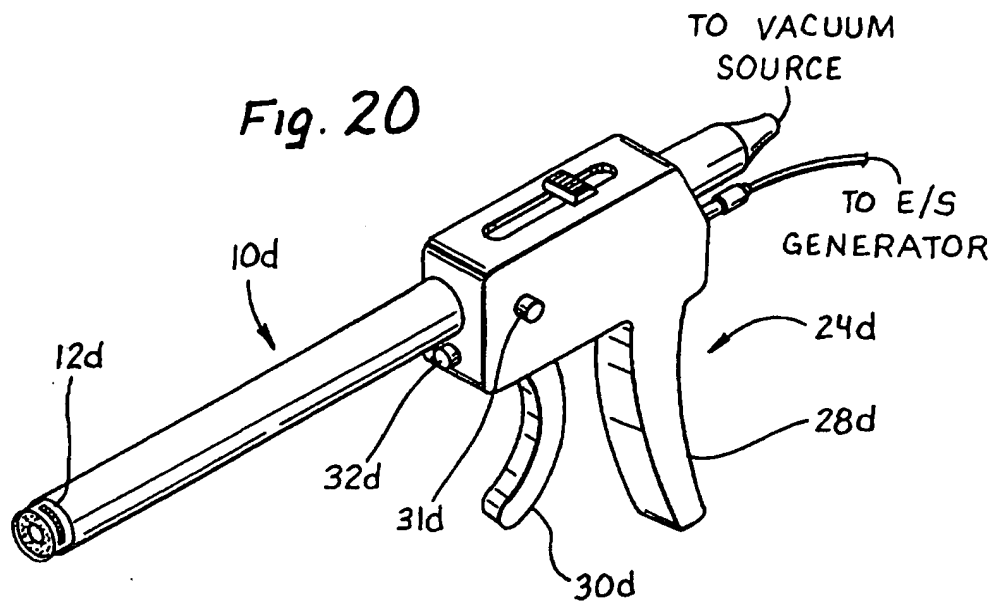
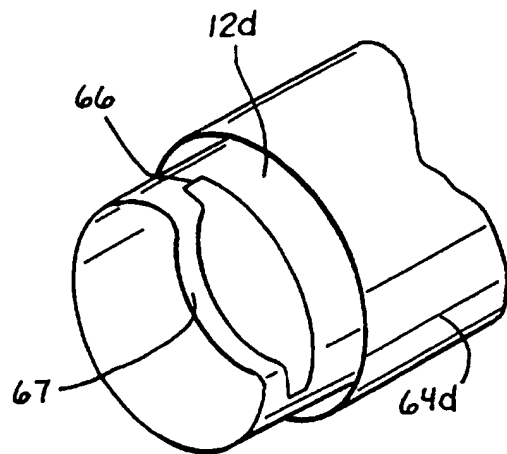
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*Fig. 16**Fig. 17*

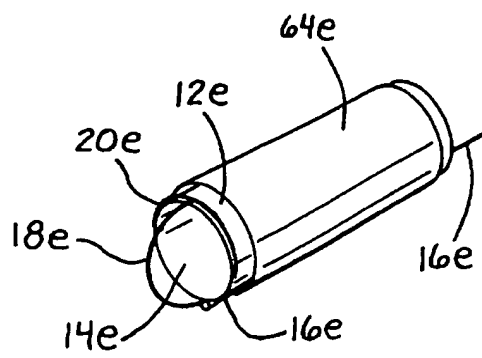
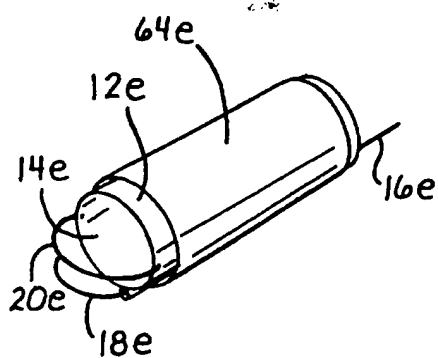
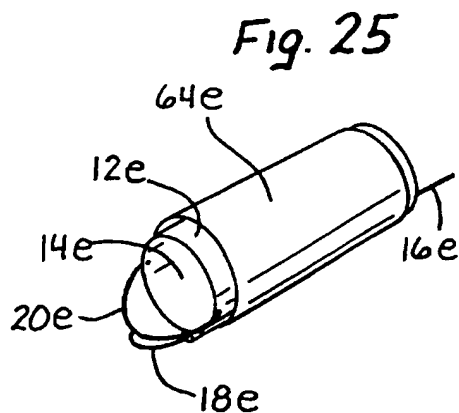
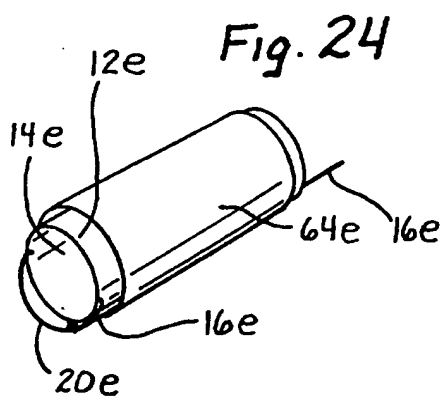
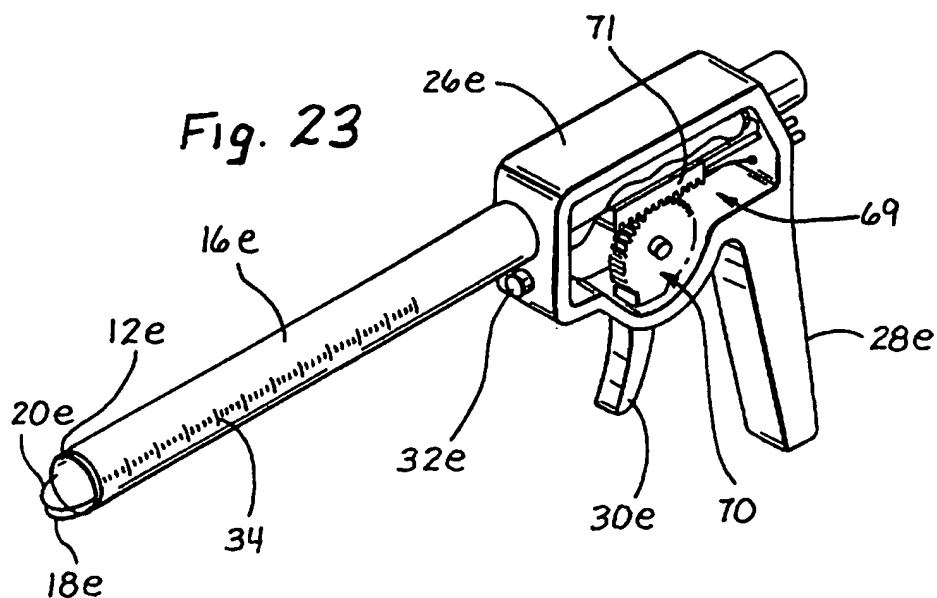
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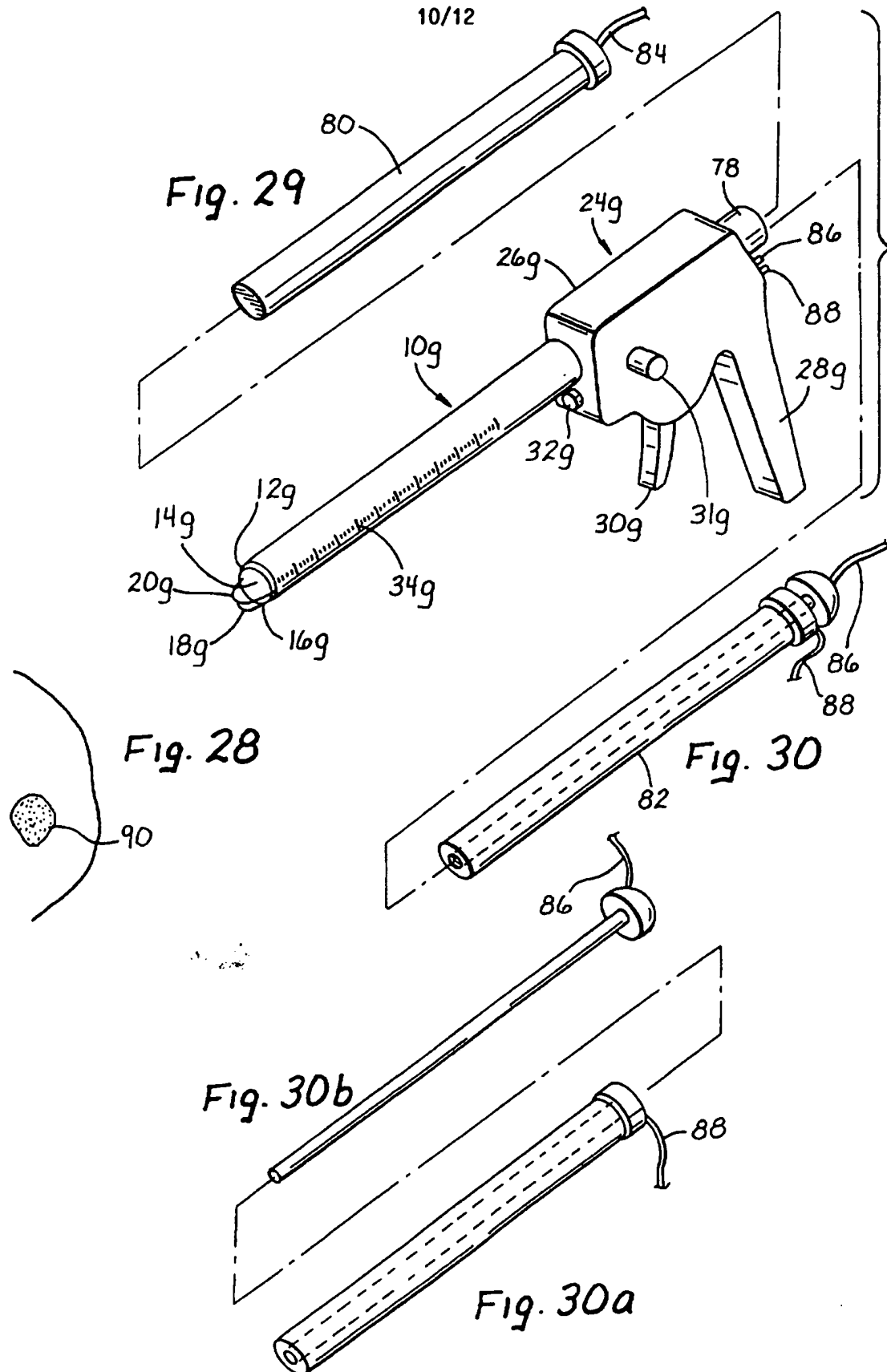


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*Fig. 21**Fig. 22*

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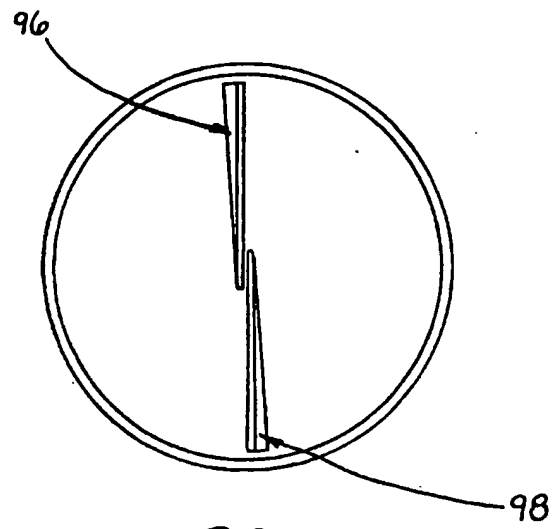


Fig. 32

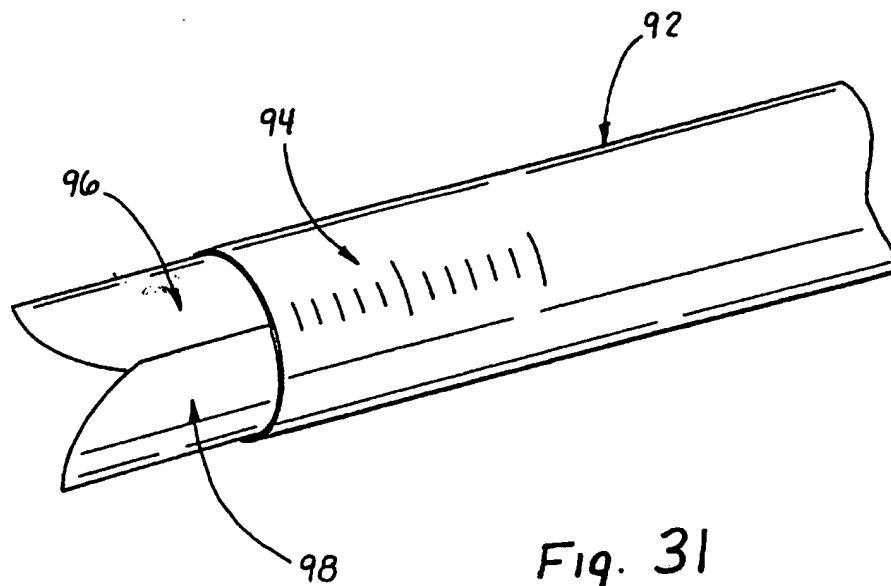
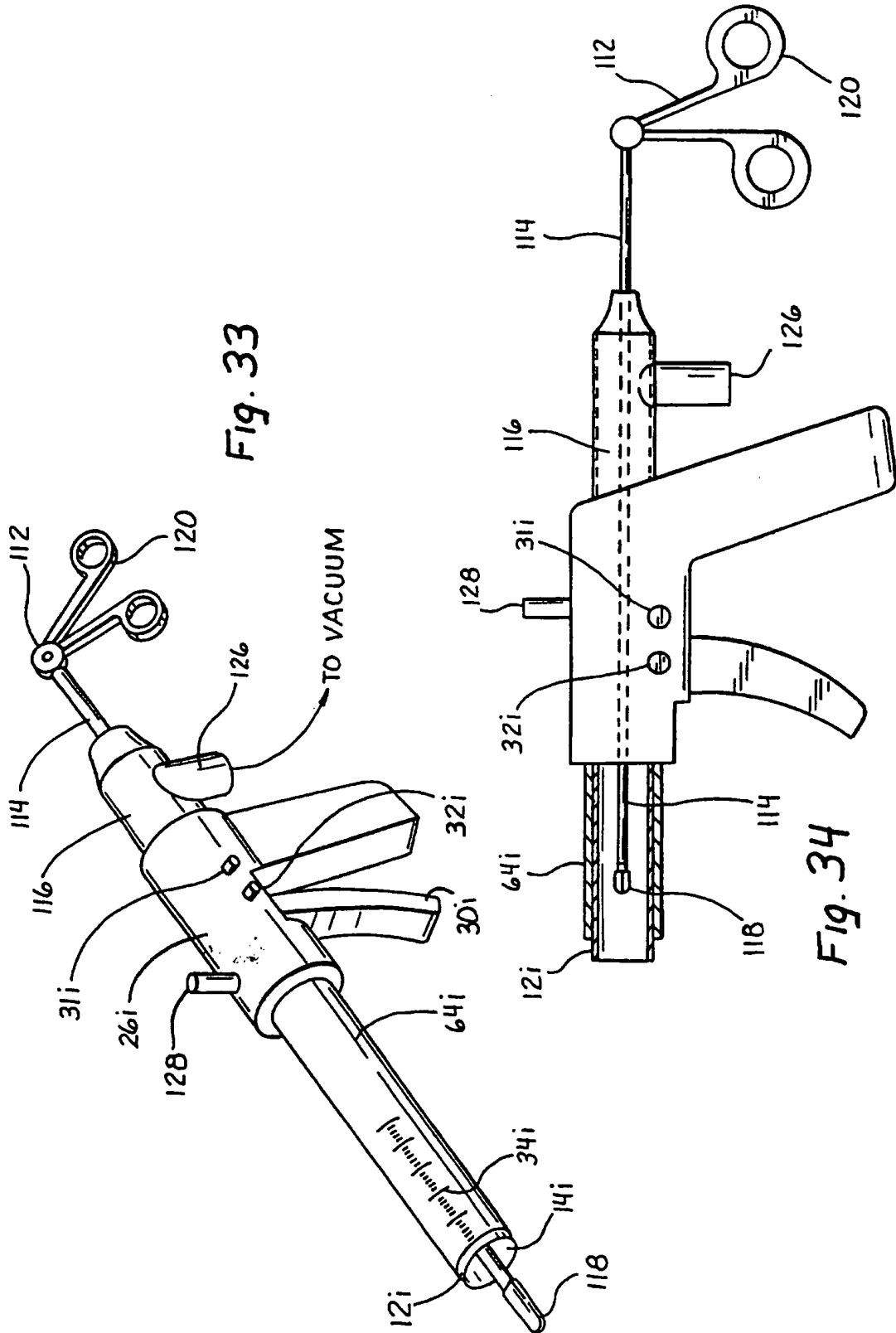


Fig. 31

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INTERNATIONAL SEARCH REPORT

In International Application No

PCT/US 97/15092

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 334 183 A (WUCHINICH DAVID G) 2 August 1994 see the whole document ---	1
A	WO 95 08291 A (BOSTON SCIENT CORP) 30 March 1995 see the whole document ---	1,13,14
A	US 5 133 360 A (SPEARS COLIN P) 28 July 1992 see the whole document ---	1
A	DE 31 48 306 A (REICH KARL FRITZ) 30 June 1983 see the whole document ---	1
A	WO 89 10092 A (METRIAS BV) 2 November 1989 see the whole document ---	1,4,21
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search 17 November 1997	Date of mailing of the international search report 24. 11. 97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Verelst, P

INTERNATIONAL SEARCH REPORT

Int'l Patent Application No

PCT/US 97/15092

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>EP 0 593 929 A (UNITED STATES SURGICAL CORP) 27 April 1994 see column 1, line 56 - column 2, line 24 -----</p>	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/15092

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 34
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PL 1/US 97/15092

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